

REMARKS/ARGUMENTS

In response to the Final Office Action mailed April 18, 2006, Applicant proposes to amend his application and requests reconsideration in view of the proposed amendments and the following remarks. In this amendment, claims 1, 6, 7 and 8 have been proposed to be amended, no claims have been cancelled without prejudice and no claims have been added so that claims 1, 2 and 4-8 remain pending.

Claim 8 was rejected as being anticipated by U.S. Patent No. 6,645,238 to Smith. (Smith). This rejection is respectfully traversed.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

Smith discloses a skids stent delivery system, and more particularly a medical device delivery catheter. The catheter comprises an inner member and a retractable sheath assembly disposed about the inner member. The retractable sheath assembly includes a sheath and at least one and desirably a plurality of skids. The skids comprise an outer layer of a first skid material and an inner layer of a second skid material.

The skids may line the entire interior of the sheath or only a portion of the sheath. For example, a plurality of spaced apart skids may be provided. The invention contemplates providing any number of skids. In one embodiment, a single skid is provided. In other embodiments, two, three, four, five, six, seven, eight, nine, ten or more skids are provided.

In the embodiment of FIGS. 2 and 3, six skids 122 are provided. Skids 122 extend from sheath 114 at junctions 130. As shown in FIG. 2, skids 122 do not dimple or become partially embedded in the openings of the stent.

In another embodiment, as shown in FIGS. 4-6, skids 122 are in the form of a tube

121 with a plurality of fingers 123 separated by gaps 131. The fingers may be straight, curved or have straight and curved portions. As shown in FIG. 6, each finger 123 includes an outer layer 124 of a first skid material and an inner layer 128 of a second skid material. The first skid material may be any of the first skid materials disclosed above and the second skid material may be any of the second skid materials disclosed above. Fingers 123 extend from collar 129. Collar 129 is desirably as short as possible. Suitably, collar is 5 mm in length or less and more suitably, 3 mm or less. Collar 129 may be attached to sheath 114 at one or more locations. Desirably, collar 129 is positioned over a proximal or distal end portion of the medical device being delivered by the catheter.

The embodiment of FIGS. 4-6 may desirably be employed in conjunction with a retractable sheath assembly which is retracted via a pull wire. As shown in FIG. 5, pull wire 113 extends proximally from collar 129.

In yet another embodiment, as shown in FIG. 7, skids 122 are arranged in a spiral. Desirably the pitch of the skids is substantially similar, if not identical, to the pitch of the stent where the stent is of spiral or helical construction.

In one embodiment of the invention, each skid is attached to the tube with fingers at a single point as shown at 130 in FIG. 2. In another embodiment, the skids are attached at a plurality of locations to the tube having fingers. In yet another embodiment, the entirety of the skids is attached to the outer layer.

Skids 122 may be bonded to sheath 114 adhesively. Suitable adhesives include UV curable adhesives such as methyl methacrylate as well as other adhesives such as epoxy, polyurethane and cyanoacrylate. Other techniques for bonding the skids to the sheath include heat bonding and laser welding techniques including those disclosed in copending, commonly assigned U.S. application Ser. No. 09/654,987. The skids may also be crimped to the sheath and held in place with ferrule 141 as shown in FIGS. 8 and 9. Ferrule 141 is disposed about retractable sheath 114, skids 122, inner member 104 and, optionally, support tube 143. Support tube 143 may optionally be provided at the distal end of inner member 104 for additional support. The optional support tube may be disposed about inner member 104 or

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interior to inner member 104. A rigid marker band may also be used to hold together the sheath and skids.

Desirably, in the various embodiments of the invention, the individual skids are 0.050 inches wide or less. Also desirably, adjacent skids are separated by 0.005 inches or more. Where three skids are provided, the skids are desirably 0.045 inches wide or less and adjacent skids are separated by 0.005 inches or more. As the number of skids is increased, desirably the width of the skids is decreased. In one desirable embodiment, the individual skids are 0.025 inches wide or less and adjacent skids are separated by 0.005 inches or more. Desirably, the distance between adjacent skids will be sufficient to prevent interference between adjacent skids when the catheter is flexed in the region of the retractable sheath assembly.

Claims 1 and 8 both claim self-expanding stent delivery systems comprising tubular shafts and tubular sheaths. The tubular sheaths each comprise an outer polymeric layer and a substantially unpenetrable and lubricious inner coating affixed to and covering the entire surface of the outer polymeric layer.

Smith discloses various embodiments of stent delivery systems comprising tubular shafts and tubular sheaths. However, this is where any similarity ends. In Smith, the sheath comprises skids which are independent features. The skids are not coatings, but rather independent elements. In one embodiment, the skids comprise a plurality of spaced apart skids. In another embodiment, the skids (plural) are in the form of a tube with a plurality of fingers separated by a gap (not covering whole surface). In another embodiment, the skids (plural) are arranged in a spiral. As can be seen from above and the Smith reference itself, there are plural skids and not a single coating covering the entire surface to which it is bonded. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, 4-7 were rejected as being unpatentable over Smith. This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant’s disclosure. In *re* Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.”

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).”

Smith discloses a device with skids and not a coating affixed to and covering the entire surface of another layer. In addition, the skids are an added component to the sheath which would tend to increase its diameter. Larger diameters in delivery devices are not desired.

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Therefore, Applicant respectfully reiterates his argument that Smith fails to disclose or even suggest the invention of independent Claims 1 and 8. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

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A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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